# Vocabulary Task Force Draft Transcript June 1, 2011

#### Presentation

#### **Operator**

All lines are bridged.

#### Judy Sparrow – Office of the National Coordinator

Thank you, operator. Good morning, or good afternoon, everybody, and welcome to the Task Force on Vocabulary. This is a Federal Advisory Committee, so there will be opportunity at the end of the call for the public to make comments—and a reminder for Task Force members to please identify yourselves when speaking.

I'll do a quick roll call. Jamie Ferguson?

#### Jamie Ferguson - Kaiser Permanente

Present.

#### <u>Judy Sparrow – Office of the National Coordinator</u>

Betsy Humphreys?

#### **Betsy Humphreys - National Library of Medicine**

Present.

#### <u>Judy Sparrow – Office of the National Coordinator</u>

Clem McDonald? I know he's there. Stuart Nelson?

#### <u>Stuart Nelson – National Library of Medicine</u>

Present.

#### Judy Sparrow – Office of the National Coordinator

Marjorie Rallins?

#### Marjorie Rallins - American Medical Association

Present.

#### <u>Judy Sparrow – Office of the National Coordinator</u>

Stan Huff? He's on. Chris Chute?

#### Chris Chute - Mayo Clinic

Present.

#### <u>Judy Sparrow – Office of the National Coordinator</u>

Marc Overhage? John Klimek? Floyd Eisenberg?

#### Floyd Eisenberg - National Quality Forum

Present.

### Judy Sparrow - Office of the National Coordinator

Don Bechtel? Holly Miller from the VA?

#### **Holly Miller - Department of Veterans Affairs**

Present.

#### <u>Judy Sparrow – Office of the National Coordinator</u>

Jim Walker? Doug Fridsma?

#### <u>Doug Fridsma – Office of the National Coordinator</u>

Here.

#### Judy Sparrow - Office of the National Coordinator

Ram Sriram?

#### Ram Sriram – National Institute of Standards and Technology

Present.

#### Judy Sparrow – Office of the National Coordinator

Andy Wiesenthal? Bob Dolin? Ken Gebhart?

#### Ken Gebhart – National Institute of Standards and Technology

Present.

#### Judy Sparrow – Office of the National Coordinator

Lynn Gilbertson? Nancy Orvis? Anthony Oliver? Marjorie Greenberg?

#### Marjorie Greenberg - Centers for Disease Control and Prevention

Here.

#### **Judy Sparrow – Office of the National Coordinator**

Did I leave anyone off? Dan Vreeman, are you on yet?

#### <u>Dan Vreeman – Regenstrief Institute</u>

Yes. I'm on.

#### Judy Sparrow - Office of the National Coordinator

Oh, good. We're waiting. All right, thank you. I'll turn it over to Jamie and Betsy.

#### <u>Clem McDonald – National Library of Medicine</u>

Did you get me? Clem?

#### <u>Judy Sparrow – Office of the National Coordinator</u>

Yes, I did. Thank you.

#### Jamie Ferguson - Kaiser Permanente

OK, well, I'll start off. And so, thank you, everybody, for joining us here today. We wanted to talk today about the need for recommending standards for the Health IT Standards Committee for lab result terminology. And we had previously recommended LOINC without specifying a particular subset. And so, I think one of the things we wanted to talk about today is the new LOINC 2000 Mapper's Guide. We have Dan Vreeman on the line to help us through that discussion.

But before we get into that, I just wanted to test: Does anybody believe that there is a standard that we should recommend other than LOINC, other than our previous recommendation, for lab result coding and for a subset to be used for EHR certification? [Pause] So, hearing none, I think it's fair to move forward with that part of our previous recommendation and then move into the discussion on subsets.

Now, previously, there were a couple of different lab result messaging implementation guides adopted that had different subsets. So the HITSP guide recommended, I believe, the 95% most frequently used

LOINC codes as reported in HEDIS for routine lab results. And then I think the ELinks guide has a different, enumerated list that is somewhat fewer LOINC codes than the HITSP guide. But in both cases, there were issues that were discussed in terms of both the publication and updating of those lists, and so those particular subsets have not moved forward. And so, what I was hoping we could do on this call is to discuss the new Mapper's Guide that has just been published that I believe everyone on the call has received in their email.

And so, Daniel Vreeman, I hope I can turn it over to you. And tell us: Just what is this new publication?

#### **Dan Vreeman – Regenstrief Institute**

Sure, I can give a brief introduction. So we've been working for a while to develop a slightly more generalizable set of the most common LOINC result codes and, in addition to that, a set of advice and guidance about how to map in those most common things to help users make good choices about which ones are appropriate for their local terminology. So previous to this, LOINC has worked with a number of collaborators, NLM, and partners in the ACLA to develop a top-300 list of order codes. And also, for a couple of years now, within the LOINC distribution and the RELMA program, we've been publishing a list of slightly more than 1,000 of the most common LOINC results codes from the Indiana Network for Patient Care data, so we developed statistics.

I have written a paper with some collaborators here that was in AMIA a couple years back. We extended that data to capture 3 years and then—was using that information within RELMA to drive this common test limit feature that was quite popular. But given that that data was only driven by the IMPC, we knew that there were some potential limitations to it. And so, we started a process to collect a much wider sample, including the IMPC, but also from Partners in Boston and UnitedHealthcare. And so we collected information from those three sources, which do have some different characteristics. Both the IMPC and Partners are probably slightly overrepresenting inpatient care by volume, but the UnitedHealthcare dataset is focused on outpatient care and is a nationwide sample, so together there's slightly more balance in that.

So there's a lot of detail that—we try to describe how we narrow down this list of top 2,000 that's in the introductory document. But in summer, we started from the set that made up 99.5% of the results from those three places but then recognized that, in those local datasets, there were a variety of terms that essentially had the meaning of "miscellaneous test." And since that wasn't a super-helpful thing to map to, we pulled those out. And so, what actually ends up in this list is somewhere closer to the top 98% by volume.

So in a nutshell, that is the origin of this dataset. And then, through careful analysis and review, we tried to create some meaningful groupings to help put the content in an easily accessible format. So we have groupings by laboratory section and then within class by certain subgroupings and then wrote up some guidance for mappers to think about, both at those parent groupings, the subgroupings, and then occasionally at the individual test level. And that is the content of the Mapper's Guide, so it's the list of all the codes organized in that grouping. Each of them has a rank so that if you wanted to sort by relative rank in terms of frequency, you could, but probably the more logical grouping is by domain. So in short, that's, I think, an overview of the document.

#### Jamie Ferguson – Kaiser Permanente

And so, let me ask: So how would you see this being used potentially to specify a subset of codes that would be used for EHR certification purposes and for testing purposes?

#### Dan Vreeman - Regenstrief Institute

Well, I think, analogous to how—so when HITSP published its list of "Here are the LOINC result codes from HEDIS," essentially my comments at the time were "I think what you want to say is, 'Any valid LOINC code should be used,' but if you want to start somewhere, start with a more generalizable, more representative set than that set was." And I think that this list now is that more generalizable and, I think, would be a very reasonable place to start or to target against certification. Now, it certainly doesn't cover all—I mean, it's a wide set of common results, and so it doesn't necessarily pick up things, for example,

that might be important for meaningful use. Now the case is like a reportable condition notification and so forth. But as far as the general purpose, what are common lab results, I think this is a good, empirically based set. And I would invite others to comment who want to comment on that as well.

#### <u>Clem McDonald – National Library of Medicine</u>

Well, what I understand from—there's a Blue Cross Blue Shield group that I think is going to adopt it—maybe the master Blue Cross Blue Shield group company or whatever they are that manages or heads up or has some connection to all the other Blue Cross Blue Shields. As you point out, it also has got a lot of text narrative on it and various places to give people an overview of what the issues are in certain phases of the lab testing. There's the issue that this does not necessarily accommodate the HEDIS strategy, which is to take every test that could have anything to do with anything related to a given condition, which is appropriate for their mission. So this is restricted to those that are frequent or have some real frequency statistics in some database. So I don't know whether there needs to be another subset for those other things. It also includes a rank, but one could thin it to make it skinnier; that number seemed too large. The problem is, for certain test spaces, you're going to run into the problem of, say—like in a blood differential count, the white count's very common, the [indiscernible] are very common, but some of the stuff that may be most interesting is less common, like metamyelocytes or [indiscernible] in case something bad. The question is if you sent an incomplete report just because those weren't included in the—if you cut it down to, say, the top 1,000. That might be a disadvantage to the utility of the lab message that came through, because you cannot arbitrarily cut out [inaudible].

#### Floyd Eisenberg - National Quality Forum

So Clem, I just had a question. This is Floyd Eisenberg. So I think I took for your message two things. One was that the set would not accommodate what's needed for value sets for HEDIS and other measures, but that wasn't the intent originally, so I can understand. But I'm concerned about the second comment you made about the less common things that have the highest clinical significance and how [indiscernible].

#### Clem McDonald - National Library of Medicine

Well, those are all in there. The last kind of thing that usually comes is a package. I guess the two big cases are urinalyses and the differential blood count. So people order a differential blood count, and if one was very restrictive on the count [indiscernible], at some point you'd strip off the last common parts of the differential that are very meaningful. I don't think it happens in the top 2,000, but I just wanted to caution about those two particularly if you wanted to constrain the number and make it more palatable. And the other side of this—so I think it's got maybe 100 or 80 allergy tests, which I don't consider necessarily very important, but there's 5,000 allergy tests in LOINC, and in different parts of the country, there'll be a different subset. I mean, it's not going to be the average allergy test, because they're not average. So I guess what you'd want to say is some large chunk of this—that for meaningful use, they'd have to accept these results and maybe more, because they want to pick others for other purposes.

But I think one also has to deal with HEDIS and public health separately, because they take the strategy of "Don't give me the common one; give me everything you've ever heard of in this space," just because they want to be absolutely comprehensive. And as we talk, there are activities under way with ELinks, which is, I think, being pretty aggressive about the public health test adding into the set. And I think the HEDIS set exists, so it could be just grabbed and run with. It exists in LOINC; it exists in HEDIS. And maybe some have to be buffered that may not get complete overlap with meaningful use; it may have to be buffered up.

#### Floyd Eisenberg - National Quality Forum

Well, I think the other issue is, HEDIS is only part of meaningful use. There are our non-antiquity measures in that set.

#### **Clem McDonald – National Library of Medicine**

I agree. You'd have to bolster it. On the other hand, there are tests in the HEDIS set that you'll never see in a lifetime because of the strategy being absolutely comprehensive.

#### Stan Huff - Intermountain Healthcare

So this is Stan. I'm trying to formulate in my mind what would be reasonable for both a certification requirement and then an approach, if you will, to meaningful use. And it comes back to what Dan said and, I guess, what we've done in our own institution. And actually, I think Doug Fridsma has commented on some of these things at different times, too. In a real working system, it's really unacceptable for us to not receive any valid LOINC order—for that matter, any valid lab test—that comes to our system.

And so, what we've done in reality is, at any point in time, we map anything that we've seen or that we know, and then we have a process in place that says if we get one of these that we don't recognize, we have people who then take that, assign a LOINC code, and set up the other things we need in our system to be able to display that lab result, and then we reprocess that record so that it shows up in the clinical record. I mean, I'm not sure how to state that, but I think that's what we would propose that people do, because I think because of the issues that Clem has point out, it's unacceptable to say, "These 2,000 are going to do everything you want," because they're going to be majors, or they're going to be clinical studies or other kinds of things that come up where you're going to say, "Well, besides those 2,000, we're going to want these other five things, and there needs to be a system for assuring that those five things are actually still legal in the process."

#### **Betsy Humphreys – National Library of Medicine**

It would seem to me that for the purposes of certification, you might want to say, "In terms of certification, you need the subset of the 2,000 (or whatever this is) most frequently seen things, and you need the reportable diseases, and you need whatever set can be identified for meaningful use measures, and that should be the test set." And then, like it says now, you get something else; you have to be able to take it in and show it to somebody.

#### Stan Huff - Intermountain Healthcare

Yeah, I think that's reasonable.

#### Clem McDonald - National Library of Medicine

Well, could someone help clarify: the target of this is the medical record systems for receiving things they ordered, or the target of this is the laboratories who are sending things?

#### Jamie Ferguson - Kaiser Permanente

No, the target is the receiving EHR, which may or may not have been the ordering system.

#### Clem McDonald - National Library of Medicine

Well, because I don't think—they wouldn't have to be able to receive all of the HEDIS tests or all of the communicable disease tests as long as they took in all of those they get that were in that set. I don't know if that makes it harder, worse, or even as reasonable. I mean, they're not going to get all of them.

#### **Betsy Humphreys – National Library of Medicine**

No, but if we're talking about a test set for a software developer, then they should be able to deal with all of them.

#### Clem McDonald - National Library of Medicine

Yeah, and that's what I'm trying to clarify: Who is the-

#### **Betsy Humphreys - National Library of Medicine**

—be able to play anything else that comes their way.

#### Stan Huff - Intermountain Healthcare

Yeah, Clem. I mean, I see what you're saying, but I'm not sure it helps me, because maybe you have a more restrictive use case, but I'm not sure I can tell a priori which ones I want and would get.

#### Clem McDonald - National Library of Medicine

Well, I mean, if you use the model that you're talking about, you would check what doesn't match and you put it in. Then you're right. I mean, I think we could actually send those lists, because some of these tests are ancient, but that's another story. You're not going to see them; no one's going to see some of them anymore.

#### **Betsy Humphreys - National Library of Medicine**

[Indiscernible]

#### Clem McDonald - National Library of Medicine

That's harder to judge, I guess.

#### Doug Fridsma - Office of the National Coordinator

This is Doug. The scope of the meaningful use regulations really is to an electronic health record, so we have the ability to certify an electronic health record that can receive a particular set of standards or to do it in a particular way. In addition, if you've got a hospital—that is, part of their electronic health record system includes the ability within their hospital to generate labs and to send those outside of the institution. That also could potentially fall within the scope of what the regulations provide for. So there is the ability to provide some guidance around the kind of information that might get sent. That's going to be primarily around hospital systems. And there's the ability to have something clearly about what is received and how that information can be received.

#### Clem McDonald - National Library of Medicine

Doug, that will be a boom, because the big commercial laboratories have already kind of staffed it pretty well, and it's the hospitals that are having trouble.

#### Jamie Ferguson - Kaiser Permanente

Yeah, but I think that most typically, in, I think, all the cases I know of, the hospital lab system is not part of the EHR; it's a separate lab system.

#### Clem McDonald - National Library of Medicine

Yeah, that's true.

#### Stan Huff - Intermountain Healthcare

This is Stanley. Unfortunately, I need to drop off, so...I think I've said most of what I know, so do the right thing. Talk to you again soon.

#### <u>Jamie Ferguson – Kaiser Permanente</u>

OK. Thank you, Stanley.

#### **Chris Chute – Mayo Clinic**

I have a question for Clem. With regard to this list of top 98 or whatever, what—I guess two questions. One is, we talked very briefly about where this list was derived. So is there an inherent bias in the list, given where the information came from? That's, I guess, the first question. And then the second question is, how frequently does this list need to be updated or changed or modified? Is it pretty stable, or is it something that, on an annual basis or whatever, you would expect there to be changes in it.

#### Clem McDonald - National Library of Medicine

They're both good questions. I think the answer to the first is that you have to assume whatever sample you pick from is going to be different by some amount than the universe. The national sample among these tests comes from UnitedHealthcare, which is a very large insurance company, and all their LOINC. But they do not include in-office tests or what ordinarily would be thought about as acute care hospital tests. Partners and the IMPC is a blend of outpatient and inpatient. They're hospital systems, so they include a lot of inpatient tests. And I think it's the total—to check with Dan—I think are just an average of the statistics from the three.

Now, we should also point out that when we did this, though we had three systems, there was not total overlap at the tail. I think there's on the order of 20%—were not common across the different sites. So if you got a fourth and a fifth, you'd probably pick up some more things. I could go on; there's lots of kind of interesting issues.

Now, regarding the redo, I guess Dan could maybe speak more with—could compare the IMPC from year to year. But the new tests come out and do take a higher position. I can't guess; I would guess it's probably 2–4%—might change—come in—big new test that comes—pop in higher. But I think the answer [indiscernible] as we try to redo it if we can get the cooperation of the same sites at least every 2 years. It takes quite a while to analyze and clean it up.

#### Dan Vreeman - Regenstrief Institute

Yeah, this is Dan. I would echo exactly what Clem says. I think certainly there's a potential for bias, and he described those issues. And I think he was right, in that I believe it was about 20% difference among those three sites, which is interesting. I don't know that we know for sure, so I would say, yes, it should be updated, but I don't know that we know or have a great estimate on how much will change over time, but I think probably that 2-year recycle is appropriate. One year might be tricky, because it actually is a fair amount of work. The ranking was derived from, just to clarify, an average of the three sources, but it's sort of relative, because clearly the sites varied in size, and so it wasn't the absolute frequency that was important; it was more the relative frequency within the set.

#### Clem McDonald - National Library of Medicine

So, Doug, what are your thoughts about—I mean, bigger than a breadbox? Smaller than a house? What are the constraints on this decision?

#### **Doug Fridsma – Office of the National Coordinator**

Well, I think there are a couple of things to think about. As you know, the regulatory process is not a particularly fast one. And one of the challenges that you have is that if you adopt a vocabulary, or if you adopt a subset of the vocabulary, and for whatever reason we made a mistake, or we left something out important, or there's a flu pandemic, and we need a new test that we need to add into that sublist, there are challenges if we've got a restrictive subset that would need to be updated through a regulatory process. And so, the good side, though, of course, is that if you have a clearly defined subset and you make sure that everybody can generate and use those codes, it's much easier, of course, to certify them.

I think we have to make sure that we think very carefully about the interplay between the standards that we adopt and the way in which we test them. So, for example, we may say LOINC is the vocabulary that is chosen for all laboratory tests, without subsetting it; but this committee may say, for the country to be successful, and for providers and hospitals and laboratory systems that may be on proprietary systems, there's a highly valuable subset that will be maintained separate from the regulatory process, but that will help people say, "Listen: If you've got these 2,000 codes or whatever, if you maintain mappings to those codes, you'll cover 98% of all the stuff that's out there."

And it may be, too, that we can think about a certification criteria, again separate from the standard, that says that you need to be able to generate 98% of the most common codes that are out there. That's the criteria, but the standard is the entire vocabulary. And so you can, in some sense, nuance or separate those things to say the certification criteria (the way in which we will assess whether people are compliant) and the standard that we want people to use could be two different things—to say the standard is one thing, but the criteria that we're going to use to assess that is that 98%. And that may change; I know, over time, that may be altered. And it may be that having that target allows people to create mappings to migrate slowly, if you will, by mapping between internal codes to this smaller subset and making it less daunting, clearly being sensitive to the number of vocabulary demands that are being made on EHR vendors at this point with ICD-10 and things like that.

So there are some ways in which we can adopt a standard, or adopt a subset of a standard, or adopt a standard and then make explicit certification criteria that we wish to apply.

#### Clem McDonald - National Library of Medicine

I think your divisions sound brilliant in terms of something that would really work.

#### Doug Fridsma - Office of the National Coordinator

Well, I think one of the things that we did in meaningful use stage 1 is, we focused a great deal on the standards. We didn't spend as much time on the certification criteria, but the thing that would be helpful from this committee is to get some guidance about "What's that fine line that we want to draw?" I mean, if we adopt a particular standard and then we say, "You need to be able to handle every possible code that might come through," it'd be pretty challenging. If we adopt a standard, however, and then we say, "The certification criteria for meaningful use stage 2 is that you need to be able to do X and Y and Z within that." We might be able to provide very strong guidance in terms of a directional statement around vocabularies and then direct resources toward making sure that people are successful in getting and meeting those certification criteria.

#### Floyd Eisenberg - National Quality Forum

Doug, this is Floyd. Can I ask a question? In prior discussions, you've mentioned something about setting a floor. So going along with your proposal, which does sound great, if your certification's based on the version as of a certain time—but if they did have more, that's still acceptable—I think that still fits. But my question is, if measures (and [indiscernible] bring it back to that) have turns in them that are not in that subset and they are required to actually calculate the measure, how do you deal with the EHRs on that level?

#### Doug Fridsma - Office of the National Coordinator

Well, I think there is an issue, and I think—I can't remember who talked about it, but we can talk about the 98% most common labs that are exchanged or that are drawn. But then there may be other things, like public health reporting or quality measures, for which we want to also include some additional vocabularies or terminology subsets to include. I think, at the end of the day—and the other piece to this, I think, is this notion of post-Elds principle, that Internet robustness principle, which is, when people generate standardized data, we want them to conform to the standard, and we want to be very, very rigorous about making sure that people generate well-formed HL7 messages and they generate well-formed transitions of care and well-formed laboratory results that have the right vocabularies and things like that. But we also want to make sure that when people receive those things—that when an EHR receives it, we want to make sure that they don't break if they get an ill-formed—or the CDC comes out with a new pandemic and we need to make sure that we've got a new test for the flu. We need to make sure that the systems don't break when confronted with a vocabulary terminology that hasn't been seen before.

And so, one of the things you can do from a certification criteria is, you can say, "If you generate a laboratory test, you have to conform and use LOINC, and you have to do all these other sorts of things that are important to making sure that you've got an explicit representation of the standard." But when you receive it and you're confronted with codes you've not seen before, you need to not break. You need to say, "A LOINC code I don't recognize." Maybe it's an incorrect LOINC code or whatever, but we need to have some way of saying, "I'm not going to break. I don't recognize this code. I've got a human-readable form that's attached to it, and I've got a way of managing that without disrupting our workflow." And again, that can be a certification criteria. Just say, "If you generate a laboratory result or if you generate a particular standard, you need to conform to the standard, and here's what it is." And if you're going to test, you have to test that you can receive not only a well-formed lab test result but also one that's got LOINC code crap that isn't part of that 98% so that, if you get a new LOINC code, you don't break as part of the sending and receiving.

#### Clem McDonald - National Library of Medicine

Can I suggest a variant idea, or maybe a weird idea, about the HEDIS and the—well, first start with the public health. Again, I've known the data on some of these. There's really a very, very large list, most of which will be relatively rare coming in. And whether one could ask the vendors to keep that list and warn when a code comes in that's not already in their system so they would have to quickly map that rather than premap it for some of the ones that are—they would map the ones that are common, and then they

would have a way to detect a code that came and it is one that they need for HEDIS. But if none of those came in, they'd never have to do anything, because a lot of the codes that are needed for HEDIS and for meaningful use would also be in the top 2,000.

#### Doug Fridsma - Office of the National Coordinator

Right, I think that's a variation on this notion of "If you get a code that you haven't seen before, don't break."

#### Clem McDonald - National Library of Medicine

Well, this one is halfway between, because you'd not break but be sure you quickly get credit for it; otherwise, you may get through in your following criteria, or you may fail three-quarters of your lookout. Now, the public health is another peculiar situation, because the truth is, currently 98% of all infectious disease reports come from laboratories. And if both places have to report, if they get a lab test from a laboratory about a reportable lab, does the receiving system have to report again, or could they assume the lab is reporting?

#### Doug Fridsma - Office of the National Coordinator

That I don't know, and I'm not sure that we've got the right folks on the call here to resolve that. But certainly that is an issue for—I know some of the work that's going on with the electronic lab reporting that CDC and, I guess, my framework there. They're discussing those issues.

#### Clem McDonald - National Library of Medicine

I'm on both those conference calls, and then at their end, for the labs, they want to get everything in from labs. But the labs now account for 98% of it.

#### Floyd Eisenberg - National Quality Forum

Yeah, this is Floyd. I just remember from practice that even though the lab's report is often something going to the clinicians to report as well—so I would check with public health to see if that's sufficient.

#### Doug Fridsma - Office of the National Coordinator

Well, typically they'll call the clinician if you get more data, so they do interact with the clinicians. But the primary report doesn't often come from them.

#### Jamie Ferguson - Kaiser Permanente

Yeah, so this is Jamie. So I think what I'm hearing is that we have perhaps a general issue I would characterize as determining the right way to have a subset that includes a variety of requirements for direct care, for public health reporting, and for quality measures. And so, how to aggregate all those different sets of requirements into a single subset is one issue.

What I'd like to do is, I want to put a hold on that for a minute in the discussion and go back to the issue of updating and the fact that requirements, whether they come in from new quality measure or from CDC or from new organisms or things that need to be tested for. I mean, there are others on the call who have far more experience with this than I do, but there are existing mechanisms for regularly updating the HIPAA code sets, for example, in a regulatory scheme. And so, is there a reason why we can't expect to update these testable subsets in a similar way? And I think we have both Marjories on this call. Maybe I could ask you two to speak to your experience there.

#### Marjorie Greenberg - Centers for Disease Control and Prevention

OK, I'm not exactly sure. This is Marjorie Greenberg. I think you're right that the industry has experience in a periodic and defined time schedule, just going to the next version of the code sets.

#### Jamie Ferguson - Kaiser Permanente

And that's on an annual basis, right?

#### Marjorie Greenberg - Centers for Disease Control and Prevention

It's on an annual basis, yes.

#### **Betsy Humphreys - National Library of Medicine**

Although not all on the same annual schedule [laugh].

#### Marjorie Greenberg - Centers for Disease Control and Prevention

Well, that's also true, because this is the ICD-9-CM. It is a fiscal year. This has to do with the congressional requirements. Now, there is actually a legislation that requires a twice-annual updating of the ICD required or justified by a new diagnosis or a new procedure that has never happened since that was passed. I mean, nothing has met that threshold. And exactly how that would be implemented, I'm not sure. But on annual basis, there are years of experience.

#### Jamie Ferguson - Kaiser Permanente

And so, to the extent that we would have some assumed relatively minor changes to the like subsets that would be published for certification testing purposes on a regular basis, does anybody see a reason why we couldn't recommend using a similar mechanism?

#### **Betsy Humphreys - National Library of Medicine**

Well, if we were using Doug's construct, which I like very much, which is "The requirement is to use the whole code set, and the testing is done against various subsets," then we're fine. But certainly, then the issue is of how up to date you want people to be. I mean, LOINC is updated how many times a year, Daniel?

#### Dan Vreeman - Regenstrief Institute

Twice, typically.

#### **Betsy Humphreys - National Library of Medicine**

And we're not in that space, but in the case of RxNorm, it is updated more frequently.

#### Dan Vreeman - Regenstrief Institute

Well, and I think, actually, to that point, if the certification criteria is that you need to be able to accommodate or receive not only the codes you know about, which might be from the previous version, but if there's an update in a new code—that you don't break when you get that. It does provide a mechanism that creates a bit more flexibility and a less rigid way in which we make sure that people can migrate from the older versions to the newer versions.

#### Betsy Humphreys - National Library of Medicine

Yes, I agree with that. And I do feel that there isn't any reason why, in some sense, there can't be a known place for any system to invoke an API and send a [indiscernible] and find out what it is if they need to do that.

#### <u>Dan Vreeman – Regenstrief Institute</u>

Sure, and I think those kinds of services become really valuable in more dynamic spaces in which there are significant updates that are being made to the codes, or if there's a pandemic or something—that we need to have a new code set developed to help track that. Those are all going to be, I think, very, very important.

#### Clem McDonald - National Library of Medicine

Well, typically, the LOINC code is returned—Dan, you'd better correct me on this—returned to the requester once it's established that it's correct, before the release time. That's how CDC, I think, has handled some stuff in the past.

#### <u>Dan Vreeman – Regenstrief Institute</u>

That's true, which is allowed, in some cases, with varying schedules of publications and dates for documents and implementation guides for the code number to get into those things, even in advance of it being published in the public distribution.

#### **Doug Fridsma - Office of the National Coordinator**

So I apologize: I'm going to have get off the call just a few minutes early. But it would seem to me that part of the discussion or part of the thing that would be helpful, I think, with regard to recommendations is not only to identify the vocabulary that might be used for a particular purpose (in this case, we're discussing LOINC and laboratory tests) but also to think about the certification criteria that we might use. And it could be that the certification criteria says both generating conforming codes and receiving both conforming and nonconforming codes or known and unknown codes, and that there may be value in creating a subset that would make people successful toward achieving those goals by constraining the problem a bit for them and providing a reduced subset that covers most of the cases and allows for people to meet the certification criteria as they move the map from maybe proprietary systems to ones that are more standard ones.

#### Clem McDonald - National Library of Medicine

Could you assert again what you said before? It seemed like a good idea, but I couldn't [indiscernible] it.

#### **Doug Fridsma - Office of the National Coordinator**

Well, the idea would be that you could adopt a vocabulary as a standard and then create a certification criteria that says that you need to be able to generate and receive the 95% pr 98% most common LOINC codes and that you also need to be able to receive any code outside of that and not break—doesn't mean that you have to be able to understand it or process it or anything else, but you need to be able to accommodate a new code and not break.

#### Clem McDonald - National Library of Medicine

Well, before you get off the phone, what do other people think of us saying more about that?

#### Marjorie Rallins - American Medical Association

This is Marjorie Rallins. I think that's a great idea—what Doug just proposed. I just think that realistically, in looking at the work that we've done for meaningful use, I don't know if users are there yet, and I think we should discuss that more.

#### <u>Clem McDonald – National Library of Medicine</u>

In terms of what he said or in terms of the meaningful use subset of the vocabulary?

#### Marjorie Rallins - American Medical Association

In terms of my experience in the meaningful use work that we've done so far. For example, if there's a new code in a value set that doesn't exist for users, I think we've had some update issues. And Floyd, if you're still on the phone, you might be able to speak to what I'm discussing at this point. So I think it's great that, for certification purposes, systems need to be able to manage codes that are not on a particular list. Is that what you're proposing, Doug?

#### **Doug Fridsma – Office of the National Coordinator**

Yeah, it's—the idea is that—and it's maybe not so true with LOINC, but it's certainly by Betsy's discussion around RxNorm, which gets updated more frequently. What you don't want to have is, you don't want the system to come to a screeching halt if there's a new code, because we're only going to be able to write regulations probably every 2 years. And that means that we either have to assume that the vocabularies will remain entirely stable for 2 years—and we know that's probably not a realistic thing—or we need to be able to say, "We believe that there will be changes that will occur over time, and we will update the regulations as we can and as it becomes appropriate." But if there's a new code that comes out that's not part of this subset or is not part of the testing criteria, we need to make sure that those systems don't break when that happens. Like I said, it doesn't mean that they have to automatically understand it, but they need to be able to say, "This is a code that I don't understand. I'm going to provide a human-readable version of what this is. I'm going to try to put the name on there, but I'm not going to try to do any decision support on it; I'm not going to try to do any sort of computer processing on it. I just want to make sure that I can convey that information in a realistic way."

And the other possibility is, suppose there is a subset that you're going to be tested against, and the laboratory performs a test for which they haven't done the mapping for that. They may send the test results not with a LOINC code but with a proprietary code that doesn't really match. We don't want that system to break; we want it to say, "This is a non-LOINC code. It's got good information that I want to convey to the doctor. I'm not going to reject the message; I'm going to try to process it as best I can." And that, I think provides a migration path for those people that may be struggling to try to convert their entire systems while we're doing ICD-10 and all these other sorts of things by saying, "Choose a constrained subset that we want you to focus on, because we think it provides a tremendous amount of value." But if somebody sends you a proprietary code or they send you a code that's a new code, just handle it intelligently and don't have your system break.

#### Clem McDonald - National Library of Medicine

And don't let the doc not see that test result.

#### Doug Fridsma - Office of the National Coordinator

Right—reject it because it doesn't conform to the very, very specific standard that you've got.

#### <u>Clem McDonald – National Library of Medicine</u>

And then the patient dies.

#### Floyd Eisenberg - National Quality Forum

Well, I agree with all that. I just want to—I have no issue with anything you just said. I think that all makes sense. Just to follow up, though, on Marjorie's comment—this is Floyd—in the meaningful use, what we found is—and measure developers experience this all the time—that they have value sets that they use, and because of comment and things that come in, periodically they want to update them. And there are some who want to use what they call intentional value sets, meaning everything that's a child of this parent code. And as the terminology changes, that's going to continue to increase or change the codes from the value set. So we just need to be able to deal with that issue. Nothing negative about any of the comments you've made; I think they're all terrific. We just have to be able to understand and be aware that these things change, sometimes very fluently.

#### Marjorie Rallins - American Medical Association

Yeah, I've been thinking about this more. I think there's two issues. I thought of system functionalities, which Doug has elegantly outlined. And then there's user, and I'm talking about human user expectations of these vocabularies and their related value sets, and I think those two are not necessarily aligned. And we can have further discussions about that user understanding of the value sets and the vocabularies and so.

#### <u>Doug Fridsma – Office of the National Coordinator</u>

I'm going to have to get off the call here. I apologize for that.

#### <u>Jamie Ferguson – Kaiser Permanente</u>

Well, Doug, thanks for your time. I really appreciate it.

#### **Doug Fridsma - Office of the National Coordinator**

Yes, and thanks again to everybody on the committee with things. I think as you go forward and you consider both the LOINC proposal—I think one thing that will be really helpful as we go into this next stage is to think not only about the standard (and the standard might be LOINC) but also the certification criteria that might be applied and how we can, in some sense, decouple those to make it incrementally possible for people to achieve meaningful use but, at the same time, send a strong directional message that says, "We want to have convergence around standards, and our life will be a lot easier, but we realize it's a fluid and dynamic place, and we want to make sure that our systems are robust enough to accommodate changes that might have occurred.

#### Jamie Ferguson - Kaiser Permanente

So Doug, this is Jamie. I have one final question before you drop off. And that is, I know you talked about a 2-year update process, which I think is based on the certification timing of the meaningful use stages. But there a reason not to consider annual updates to the vocabulary subsets that are used regardless of the update of general certification criteria?

#### Doug Fridsma - Office of the National Coordinator

Well, I think we certainly could consider something along those lines. I think we would want to see if it's possible to create a regulation that says, "The certification criteria's the 98% most common as determined by X." And on an annual basis, that could be updated in a subregulatory fashion. We would need to work pretty closely with the Office of Policy and Planning and Steve Posnack and others to make sure that we've got the language right with that. But I think, when it comes to regulations, it takes a fair amount of effort to do that, because it takes a fair amount of time to do that. If there are mechanisms that—we can achieve the outcomes that we desire and the agility that we need; we just need to find the right mechanism to do that. If it's a regulatory process, that'll be great; if not, there may be other mechanisms that could be even more agile.

#### Jamie Ferguson - Kaiser Permanente

OK, thanks.

#### **Doug Fridsma - Office of the National Coordinator**

OK, guys, so listen: Thank you so much. I'm going to drop off now.

#### Jamie Ferguson - Kaiser Permanente

So perhaps we can turn back to the question of how to create or how to recommend a subset that would include the, for example, the requirements of the different quality measures that may not be in the 2,000.

#### Floyd Eisenberg - National Quality Forum

So this is Floyd. One potential way—although I say that as potential—is to collect all of the lab value sets from the meaningful use measures. But my question is, since we were actually asked to retool 113, would we be looking for all those among the 113 measures? The other concern is, we're still updating those, because we're still resolving comments. The comment resolution ended April 1, and we're having review panels over some of this, so we'll have that later this year. So that's an option if you wanted to include that as a measurement subset. What I will say is, that won't necessarily cover every other measure for 2013 that has not yet been developed.

#### <u>Clem McDonald – National Library of Medicine</u>

Well, it sounds like a good idea to make it a separate package, both because of the timing and because of the differences. But how much is that different from the laboratory test? How much is it different from the HEDIS? Are there 20% more content or subjects or disease states? Because it just takes everything there is for a given thing; like, for gonorrhea, it takes every test code just about that exists for gonorrhea.

#### Chris Chute - Mayo Clinic

Yeah, so for any measure that is in HEDIS and was retooled, they're identical, unless they updated one or two. But that's only for about 25 or so measures. Of the other 113, they're from other stewards. And there may be some overlap but not a lot—what the other kinds of labs look for.

#### Clem McDonald - National Library of Medicine

And there are also labs in the other 113/125?

#### Chris Chute - Mayo Clinic

I'm just pulling a number out of the air: I'd say about 30–40% of them. I can't remember for sure. They're not all.

#### Clem McDonald - National Library of Medicine

So there's some work involved.

#### Chris Chute - Mayo Clinic

Yes.

#### Clem McDonald - National Library of Medicine

Because at HEDIS, they do the—that's absorbed already. It happens annually.

#### **Chris Chute - Mayo Clinic**

Well, the other challenge is in updating the measures. We're doing an update this year at the request of CMS. I don't know that there's an update to value sets scheduled yet, starting next year on an annual basis.

#### Floyd Eisenberg - National Quality Forum

Jamie, what's the next step?

#### Jamie Ferguson - Kaiser Permanente

Well, I'm just trying to grapple with the idea of how to put these things together into a recommendation. I'm not having any particularly brilliant ideas right now.

#### Clem McDonald – National Library of Medicine

I thought I heard one from Doug: that we'd say—I mean, I don't want to put words into anybody's mouth, but—that LOINC would be the vocabulary used, and then the requirements for testing would be—I think you'd break this into two or three pieces—the 98% LOINC codes for receiving routine results from labs, and then the package that'll come out of the quality assurance would be another package, and whatever public health comes up.

#### Jamie Ferguson - Kaiser Permanente

Yeah, I think we're in a pretty violent agreement. The only thing that I would put on as perhaps a friendly amendment to that is that I think we have to recommend essentially one subset package that is a superset of those different things.

#### Betsy Humphreys - National Library of Medicine

Jamie, this is Betsy. I think there's no problem with us packaging it into a single subset. But the issue, of course, is that you might do very different things with the more frequently used subsets than you do with the others. For example, you might be doing things related to them that would have some impact on data creation, or you might—things with the frequent ones—you might deal with them differently than the ones that you might see in a blue moon. So you could put them in the same place, but I think you would want a tag so that people knew what they were looking at and have that frequency information so that they could do something sensible with it in the design of certain capabilities within their systems.

#### <u>Jamie Ferguson – Kaiser Permanente</u>

Yeah, and that's a great point. I guess I wasn't thinking that there was such a variety of different kinds of certification tests for different functionality for different subsets.

#### **Betsy Humphreys – National Library of Medicine**

But the issue, to my way of thinking, would be "Well, you could certify; well, can you read all of these?" And that's fine, but we would want to be—I mean, you could imagine that within an EHR, there would be certain functionality, and it might operate more quickly and better if it was only running—if it was privileging the subset, for example, that was really used to report to the health department, as opposed to the other 2,000.

#### Marjorie Rallins - American Medical Association

Well, Jamie, this is Marjorie Rallins. Your reason for the superset was...?

#### Jamie Ferguson - Kaiser Permanente

Well, so I think—let's say that, in the first place, there's likely to be a lot of overlap for the different subsets.

#### Clem McDonald - National Library of Medicine

There won't be a lot, actually; it'll probably be 10%. I've looked at some of this. There's maybe eight gonorrhea codes in the top 2,000, and I think there's 30 or 40 of them in the public health one. There's a lot of tail stuff, because the tail's chopped off of the top 2,000, and it's not from those other sectors. And the other reason that we think of them, at least conceptually, separately is because they seem to have different schedules of when they really can be available.

#### Jamie Ferguson – Kaiser Permanente

What comes to mind for me is that, in order to have this conversation about really whether it's appropriate to have multiple subsets of LOINC or just one, we really have to know what the certification tests are that the subset would really be used for.

#### Betsy Humphreys - National Library of Medicine

And because I suppose what you could say is, "Here's the certification set, but on the other hand, here's these other subsets," and you might care more about those when you're actually trying to put certain types of functionality into your product. If the certification test is only saying, "You recognize all these valid codes; can you interpret them properly?", no matter what the function, I see what you mean: That could be one undifferentiated set. But if you're designing the coolest, best way for your system to report to public health, you might want it to be segmented in a different way. Or if you're designing the capability to compute the measure, you're going to be dealing with those things in chunks anyway.

#### Jamie Ferguson - Kaiser Permanente

So actually, I think this is really a very important point. What I'm going to suggest is that we try to get onto our next call one or more people who are very familiar with the plans for the certification tests.

#### **Betsy Humphreys – National Library of Medicine**

And that was NIST people, too; wasn't it?

#### Jamie Ferguson – Kaiser Permanente

Exactly.

#### **Betsy Humphreys - National Library of Medicine**

Sounds like a good idea.

#### Jamie Ferguson – Kaiser Permanente

Yeah. I mean, I think that's really necessary.

#### **Betsy Humphreys - National Library of Medicine**

I mean, we've got this also in relationship to RxNorm, since we've been through that already.

#### Jamie Ferguson – Kaiser Permanente

Yeah. I mean, my understanding, frankly, was that the certification testing just revolved around incorporating structured data into the EHR to be used for treatment purposes.

#### Clem McDonald - National Library of Medicine

This gets easier, a lot easier.

#### Jamie Ferguson - Kaiser Permanente

Well, exactly. But at the same time, if we want to have one subset that's going to be used for one functional certification test, then that's why I was thinking we'd want to have that one subset include everything.

#### Clem McDonald - National Library of Medicine

Getting back toward Betsy's point, building up master files of what the receiving system will receive—a concept, whatever code it is, is a [indiscernible], especially if these are existing systems. And so, I just fear that if we give them a huge pile of tests that they mostly don't see, there could be resistance to that in

our work. And in the case of public health—and Marjorie, I'm for public health—the national benefits to receiving back—to send back those test codes that are public health required—that the 98% will be already sent by the lab and send it to them—is also a lot of overhead that it's probably not going to do them that good. It may not hurt, though, that I guess—warn the doc that you've got one of these. But that all is to agree with what everybody's saying about this agreement.

#### **Betsy Humphreys - National Library of Medicine**

I think, then, we just have a different—if one is going to work for testing (and we can involve NIST and find out), then we just need to realize it's a potential additional education piece for the EHR developers that—"Yes, here's this file that's used in testing," but if you're really trying to build a smart system that does good things for particular purposes, you may not want to treat it as an undifferentiated list in your system.

#### Ken Gebhart - National Institute of Standards and Technology

Hi, it's Ken Gebhart at NIST. Can I catch up for a second? I just want you to know we're listening to the conversation and thinking about how testing would be done given the targets you have in mind.

#### Jamie Ferguson - Kaiser Permanente

So Ken, do you think that you or someone else from NIST could join us on our next scheduled call (I can't remember the exact of that one; I think it's in a couple weeks) to talk about how these one or more subsets might be used in certification testing for stage 2?

#### Ken Gebhart - National Institute of Standards and Technology

Yeah, I was actually trying to find the next meeting on the calendar just so that I know when it is.

#### **Judy Sparrow – Office of the National Coordinator**

Yes, June 24.

#### Jamie Ferguson – Kaiser Permanente

Also, to clarify exactly what the focus is on for the [indiscernible]. The focus is on receiving results through teen care.

#### Ken Gebhart – National Institute of Standards and Technology

Yeah, we'll be on the call. Ram is on the call as well. We'll get some thoughts together. I think you just raised some of the questions that we need to get to the bottom of, because if I think about the current set of criteria, there are ones that require the EHR be able to generate an appropriate code, an output of a message or a document. There are others that require that it be able to receive a code. And I think the upward side is, a pretty straightforward conversation about testing could be extensive. The [indiscernible] side—I'm a little bit more—I think more conversation would be helpful about "What do you actually want to evaluate in terms of the system's behavior?" We talked about essentially receiving lender even if you don't know what the code means. So that's my version of Doug's "Don't break if you get a code you don't know." But I think beyond that, we ended up in conversations about "Do we expect EHRs to be able to receive and store and then operate decision support logic, for example, against those codes?" And that gets a little more complicated when you start thinking about "Well, what do you want to test for?" Well, I'll be glad to start that conversation with you during the next call.

#### Clem McDonald - National Library of Medicine

Is some of that pre-specified in some regulatory or previously written document that we don't have a choice in, or are we figuring out ourselves?

#### **Betsy Humphreys – National Library of Medicine**

I think the latter.

#### Ken Gebhart - National Institute of Standards and Technology

I think so, too.

#### **Betsy Humphreys - National Library of Medicine**

[Laugh] Isn't that wonderful?

#### Clem McDonald - National Library of Medicine

Yeah, be careful what you wish for.

#### Ken Gebhart - National Institute of Standards and Technology

The good news is that at least there's one person with the experience I've seen the need to do testing like this for EHRs actually being implemented and talking to lab systems. The bad news is, it's pretty rigorous and maybe more extensive than...

#### Clem McDonald - National Library of Medicine

Well, if you ask—if I could make an early suggestion about your last question—is that I think the minimum is that you could store it and display it in a flowsheet. And it's a kindred of another thing with the same code. That's probably the minimum you're likely to be able to get out of it, so you could actually flowsheet results from different lab sources.

#### Ken Gebhart - National Institute of Standards and Technology

Yeah, and that's a good point, and you're right into the sweet spot of the conversation that I think is murky, because we have to sort through what other behaviors we've actually expected to be able to do.

#### Clem McDonald - National Library of Medicine

This isn't where it just gets wildly trickier, because then you also have conformance on the code for the answers, and you don't understand the units, probably.

#### Ken Gebhart – National Institute of Standards and Technology

Oh, yeah, sorry. [Laugh]

#### Clem McDonald - National Library of Medicine

[Indiscernible] off, although good systems could do that.

#### Ken Gebhart - National Institute of Standards and Technology

Yeah. I think I'll end up going back to a conversation, perhaps with Doug, about Paul's [indiscernible] how much to tackle this stage versus some later stage. Anyway, I'm listening; I think it's a great conversation, and we'll be prepared to help guide this discussion at the next meeting.

#### Jamie Ferguson - Kaiser Permanente

OK, good. Well, thank you. And thanks, everybody, for this conversation.

Now, are there other things that we should discuss here on this call, or have we run the course of this discussion today? Are there any questions, while we have Dan on the line, for top 2,000? Any questions about that in particular?

#### **Betsy Humphreys – National Library of Medicine**

I have a comment: It's great to have it. Thank you.

#### Clem McDonald - National Library of Medicine

Yeah, thank you.

#### **Chris Chute – Mayo Clinic**

We're certainly open to feedback, too. And so [indiscernible] get a chance to look at it and...

#### Jamie Ferguson - Kaiser Permanente

OK, then I think that's it for this call. And Judy, do we want to check for public comment?

<u>Judy Sparrow – Office of the National Coordinator</u>
Sure. Operator, can you check and see if anybody wishes to make a public comment?

#### **Operator**

Yes. If you're on the phone and would like to make a public comment, please press \*1 at this time. If you are listening to your speakers, you may dial 1-877-705-2976 and press \*1 to be placed in the comment queue. [Pause] We do not have any comments at this time.

#### <u>Judy Sparrow – Office of the National Coordinator</u>

Thank you, operator. And thank you, Jamie and Betsy

## <u>Jamie Ferguson – Kaiser Permanente</u> Thanks, everybody.